

AMENDMENT TO THE DRAWINGS:

Please replace the original drawings with the attached replacement drawings (Figs. 1-38).

REMARKS

Claims 164-182 are pending in this application. Claims 1-163 has been canceled without prejudice or disclaimer. Claims 164, 181 and 182 are amended for clarity to recite that "first solvent has a Flory interaction parameter (χ value) that is not sufficient for gelation". Claims 164 and 182 are amended to recite "form a biocompatible physically cross-linked hydrogel without chemical cross-linkers, irradiation or thermal cycling". Claims 172, 173, 178, 179, and 181 are amended to recite that "the cross-linked biocompatible hydrogel is formed without chemical cross-linkers, irradiation or thermal cycling." Claims 164-180 are amended for clarity by adding the term "biocompatible." Support for the amendments can be found throughout the specification, see for example, page 9, lines 22-23, paragraphs bridging pages 13 and 14, and 25 and 26. Therefore, no new matter is introduced. The Office Action is discussed below:

Specification:

The abstract of the disclosure is objected to because it is not within the range of 50 to 150 words. Applicants herewith submit a single paragraph in a separate sheet to substitute the Abstract filed on January 30, 2006.

Drawings Objection:

The examiner requires submission of replacement drawings, because the current drawings are blurry, indistinct, and difficult to discern.

Applicants herewith submit a complete set of replacement drawings, Figures 1 through 38.

Anticipation Rejection:

On pages 2-4 of the Office Action, the examiner rejects claims 164-169, 172-175, 178, and 180 under 35 U.S.C. 102(b) allegedly as being anticipated by U.S. Patent No. 6,268,405 to Yao *et al.*

On page 5 of the Office Action, the examiner rejects claim 179 under 35 U.S.C. 102(b) allegedly as being anticipated by U.S. Patent No. 5,047,055 to Bao *et al.*

Applicants respectfully disagree with the examiner and invite the examiner to consider the MPEP that:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

See MPEP § 2131, Rev. 6, September 2007 at 2100-67.

In order to assist the examiner in distinguishing the claimed invention from the cited references (Yao *et al.* and Bao *et al.*) and clarify that none of the cited references disclose each and every element recited in the claims, applicants submit:

U. S. Patent No. 6,268,405 (Yao et al.) does not disclose a product nor a process that is relevant to the claims:

Yao patent deals with PVA-based hydrogels formed from a freeze-thaw process. Yao describes the incorporation of various metallic salts in solid form and various 'dopants', which can include PEG. The dopants are included as a mechanism to form pores (see col. 1, lines 40-46), and are not described as a mechanism to aid in crosslinking. In fact, Yao specifically states that too high of a dopant concentration will have an adverse effect on the hydrogel formation process (see col. 7, lines 54-58) and hence their preferred PEG concentration range is 3-8% (see col. 7, lines 58-62), which is well below the concentration range used in the instant application, which also is a concentration range that would not yield gelation. Yao's gel's are cross-linked by

thermal cycling, that is by freeze-thaw gelation (see col. 9, line 58 to col. 10, line 21). The Flory interaction parameter as recited in claim 164 is nowhere disclosed in the Yao. Also, Yao does not use the dopant to cause gelation. As such, Yao material is not suitable for injection into a body cavity that cannot handle a further freeze-thaw process. Furthermore, regarding claims 167-169, Yao never discusses salt solutions, particularly those in the concentration described in the instant application. In fact, Yao states that the salts are preferably ground to a powder form (see col. 7, lines 15-19). Consequently, Yao process and the materials disclosed are of no relevance to the claimed invention.

Moreover, as discussed above, the claimed physically cross-linked biocompatible hydrogels are physically and structurally superior than the gels made by Yao process. Claimed physically cross-linked biocompatible hydrogels also are highly suitable for *in vivo* use and possess superior characteristics that they are suitable for injection into a body cavity. Instantly claimed hydrogels are made without thermal cycling. Therefore, instant physically cross-linked biocompatible hydrogels made by the processes recited in the claims are different than the gels disclosed by Yao.

Furthermore, without acquiescing in the rejection, in order to expedite the prosecution and for additional clarity, applicants amend claims 164, 172, 173 and 178 as noted above.

Accordingly, Yao does not disclose each and every element recited in the claims 164, 172, 173, or 178 or any claims dependent thereof. Therefore, claims 164-169, 172-175, 178, or 180 are not anticipated by Yao *et al.*

U. S. Patent No. 5,047,055 (Bao et al.) also does not disclose a product nor a process that is relevant to the claims:

Bao *et al.* also discloses a PVA-based hydrogel formed from a freeze-thaw process, and formed specifically for a nucleus pulposus prosthesis. Solvent manipulation through changes in the Flory interaction parameter are not disclosed in

Bao *et al.* Therefore, as clarified above, the instant physically cross-linked biocompatible hydrogels made by the processes recited in the claims are different than the gels disclosed by Bao *et al.*

Thus, as discussed above, Bao *et al.* does not disclose each and every element as recited in claim 179. Accordingly, claim 179 is not anticipated by Bao *et al.*

However, without acquiescing in the rejection, in order to expedite the prosecution claim 179 is amended to recite "a biocompatible cross-linked polyvinyl polymer hydrogel" and that "the cross-linked biocompatible hydrogel is formed without chemical cross-linkers, irradiation or thermal cycling", which further distinguishes the claimed invention from Bao *et al.* that requires thermal cycling, such as freeze-thaw, among other things. Yet, Bao *et al.* does not disclose a biocompatible cross-linked hydrogel that is suitable for *in vivo* use. Support for the amendment can be found throughout the specification (see for example, paragraph bridging pages 25 and 26).

Obviousness Rejection:

On pages 5-6 of the Office Action, the examiner rejects claims 170, 171, 176, and 177 under 35 U.S.C. 103(a) allegedly as being unpatentable over U.S. Patent No. 6,268,405 to Yao *et al.* in view of U.S. Patent No. 5,091,121 to Nakada *et al.*

Regarding Yao, applicants refer to above clarifications, made in response to the alleged anticipation rejection, that Yao does not disclose each and every element recited in the claims 164 or 172 or any claims dependent thereof. Claims 170 and 171 are dependent of claims 164, and claims 176 and 177 are dependent of claim 172.

U. S. Patent No. 5,091,121 (Nakada *et al.*) describes a method of making balloons for intraocular lenses. The examiner relies on Nakada that describes injecting various materials, including hyaluronic acid and polyacrylic acid into a balloon to form a lens. However, the reagents described in Nakada are not used as gellants, nor are they

causing gelation of a base vinyl polymer solution. Therefore, there is no teaching in Nakada to use hyaluronic acid or polyacrylic acid in a gelation process to arrive at the claimed product. Besides, coupled with the fact that Yao does not use solvent manipulation to form a cross-linked hydrogel, thus, even if these references are combined, would not arrive at the claimed product. Accordingly, Nakada does not rectify the deficiencies of Yao, as discussed above, and therefore a combination of the cited references does not make the claimed invention obvious.

However, without acquiescing in the rejection, in order to expedite the prosecution, applicants amend claim 164 to recite that "the first solvent has a Flory interaction parameter (χ value) that is not sufficient for gelation" and "the second solvent having a higher Flory interaction parameter (χ value) than the vinyl polymer solution that is sufficient for gelation in order to form a biocompatible physically cross-linked hydrogel without chemical cross-linkers, irradiation or thermal cycling....", and claim 172 to recite "the cross-linked biocompatible hydrogel is formed without chemical cross-linkers, irradiation or thermal cycling", which further distinguish the claimed inventions from the cited references.

Therefore, Yao in view of Nakada does not make the claimed invention obvious.

On pages 6-8 of the Office Action, the examiner rejects claims 181 and 182 under 35 U.S.C. 103(a) allegedly as being unpatentable over U.S. Patent No. 5,047,055 to Bao *et al.* in view of U.S. Patent No. 6,268,405 to Yao *et al.*

Regarding Bao and Yao, applicants refer to above clarifications, made in response to the anticipation rejection, that none of the references disclose each and every element recited in the claims. Also, because neither Bao nor Yao use solvent manipulation to form a biocompatible cross-linked hydrogel, no combination of these two references would arrive at the claimed product.

In this context, applicants point out that the applied references must teach or suggest all claim limitations. Applicants submit that the rejections do not meet this test and refer the examiner that:

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

See, MPEP § 2143.03 at 2100-142 (Rev. 6, September 2007).

However, without acquiescing in the rejection, in order to expedite the prosecution and for additional clarity, applicants amend claims 181 and 182 to recite that "the first solvent has a Flory interaction parameter (chi value) that is not sufficient for gelation" and as described above. Therefore, Bao in view of Yao does not make the claimed invention obvious.

Further, as discussed above, even if the cited references were combined, the resulting product would not meet all claim limitations. Accordingly, Yao *et al.*, Bao *et al.*, and/or Nakada *et al.* disclosure, or any combination thereof, do not make the claimed inventions obvious.

In view of the above, applicants request withdrawal of the obviousness rejection.

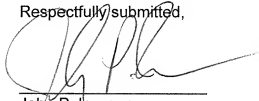
REQUEST

Applicants submit that claims 164-182 are in condition for allowance and request consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Attachments: Replacement Drawings
(Figs. 1-38)

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Date

Respectfully submitted,



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